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10/560,210	05/05/2006	Robert Short	P-7717	2947

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EXAMINER	
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1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,210	SHORT ET AL.	
	Examiner	Art Unit	
	SHAFIQUL HAQ	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-84* is/are pending in the application.

4a) Of the above claim(s) *47,48,54,56-61,63-66,69 and 73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-46,49-53,55,67-68,70-73 and 74-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Election-Restriction

1. Applicants' election of species filed July 10, 2008 in response to Office Action of June 11, 2008 is acknowledged and entered. Applicants' elected "cells" as the binding entity, "carboxyl group" as the functional group of the binding moiety, "carboxylic acid" as the plasma monomer and "plastics" as the substrate. Claims 44-46, 49-53, 55, 62, 67-68, 70-72 and 74-84 read on the elected species. Accordingly, claims 47-48, 54, 56-61, 63-66, 69 and 73 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
2. Claims 44-46, 49-53, 55, 62, 67-68, 70-72 and 74-84 are examined on merits in this office action.

Claim Objections

3. Claims 44 and 78 are objected to because of the following informalities: Claim 44 and 78 recites "a substrate/surface obtainable by". The term "obtainable" is not a positive recitation and thus Applicants are suggested to change the term to "poduced by" or "obtained by" to positively recite the process used to prepare the substrate.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 44-46, 49-53, 55, 62, 67-68, 70-72 and 74-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 44 recites “monomer from a monomer source” and “two spatially separated monomer sources” in lines 2-3 and 5-6 respectively. The “monomer source(s)” is not clearly defined in the specification and therefore, the structure (chemical composition) and the “source(s)” of the monomer is vague and indefinite.
7. Claim 67 recites "the compound" in line 1. Claim 67 is dependent on claim 61 and is unclear what compound of claim 61 is referred to by the recitation "the compound".
8. Claim 75 is indefinite for reciting “ethylene-oxide type monomer” in line 2 because it was unclear what "type" of ethylene-oxide monomers are intended to convey. The addition of the word "type" to an otherwise definite expression extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver,*109 USPQ 118 (Bd. App. 1955).
9. With regard to claim 78, the nature and structure of the “non-uniform plasma polymer surface” is unclear and it is also not clear what is intended to mean by “non-uniform”. Non-uniform with respect to what? Chemical nature? Structure? Shape?
10. Claim 80 recites "wherein the system is part of an assay product". It is not clear what product on an assay is encompassed by "an assay product" wherein the cell culture system is a part of that “assay product”.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 44, 45-46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Goessl *et al* (J. Biomater. Sci. Polymer Edn. 2001).

Claim 44 is a product-by-process claim and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Goessl *et al* disclose a substrate having a pattern of areas with affinity for cells prepared by taking a surface having a pattern of fluorocarbon plasma polymer and applying thereto a surfactant conjugated peptide. The peptide is thus immobilized on the surface, in a pattern via the surfactant which has a strong affinity for the fluorocarbon polymer (see abstract). Therefore, Goessl *et al* disclose a surface of a substrate having a plasma polymer deposited thereon in a non-uniform way and on that non-uniform surface a binding entity (the peptide).

With regard to claims 45-46, Goessl *et al* disclose, Goessl *et al* disclose that the surface binds to cells, which comprises carboxyl or amine functional group (i.e.

binding entity) (see abstract) and with regard to claim 49, Geissl *et al* teach substrate comprising amine functional group (amine containing molecule: e.g. histamine) capable of interacting covalently with a binding entity (e.g. cell).

13. Claims 78 is rejected under 35 U.S.C. 102(b) as being anticipated by Goessl *et al* (J. Biomater. Sci. Polymer Edn. 2001).

Claim 78 is a product-by-process claim and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Goessl *et al* disclose a cell culture system comprising a substrate having a pattern of areas with affinity for cells prepared by taking a surface having a pattern of fluorocarbon plasma polymer and applying thereto a surfactant conjugated peptide. The peptide is thus immobilized on the surface, in a pattern via the surfactant which has a strong affinity for the fluorocarbon polymer (see abstract).

Therefore, Goessl *et al* disclose cell culture system comprising a surface of a substrate having a plasma polymer deposited thereon in a non-uniform way.

14. Claim 78 is rejected under 35 U.S.C. 102(e) as being anticipated by Kanbe *et al* (US 6,733,868).

Claims 78 is a product-by-process claim and even though product-by-process claims are limited by and defined by the process, determination of patentability is

based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113. The cell culture system that includes a surface obtainable by the process as claimed would comprise a substrate comprising a non-uniform plasma polymer on the surface of the substrate (i.e. a non-uniform plasma polymerized surface).

Kanbe *et al* disclose a substrate comprising pattern of thin film on the surface of the substrate such that the surface have a pattern of affinity region having an affinity to fluid and a non-affinity region, not having affinity for the fluid (see abstract). Kanbe *et al* also teach pattern of plasma polymerized film (see fig. 9) prepared by masking and plasma irradiation of the unmasked region to provide cross-linked layer with un-reacted groups, which provides polar hydroxyl and carbonyl group upon exposure to air or oxygen (Column 14, lines 1-67). Kanbe teach that the polar group have and affinity to fluid containing polar molecules (column 14, lines 9-10). Therefore, Kanbe *et al* disclose a substrate wherein the substrate comprises a non-uniform plasma polymerized surface.

With regard to the recitation "A cell culture system", Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to

a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Kanbe *et al* teach that the invention provides a region of the surface of a substrate having an affinity to a fluid and a region not having an affinity to a fluid (column 14, lines 9-10 and column 24, lines 52-57) and the affinity surface of Kanbe *et al* is capable of binding to cell(s) and is capable of performing as a cell culture system.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 44-46, 49-53, 55, 62, 67-68, 70-72 and 76-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanbe *et al* (US 6,733,868) in view of Haddow et al (WO 03/035850) and Uhrich et al (US 2003/0104614).

Claims 44 is a product-by-process claim and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113. The substrate of

claim 44 that is obtainable by the process as claimed would comprise non-uniform plasma polymer on the surface of the substrate (i.e. a non-uniform plasma polymerized surface) wherein at least part of the plasma polymerized surface is bound to a binding entity providing a non-uniform surface of binding entity.

Kanbe *et al* disclose a substrate comprising pattern of thin film on the surface of the substrate such that the surface have a pattern of affinity region having an affinity to fluid and a non-affinity region, not having affinity for the fluid (see abstract). Kanbe *et al* also teach pattern of plasma polymerized film (see fig. 9) prepared by masking and plasma irradiation of the unmasked region to provide cross-linked layer with un-reacted groups, which provides polar hydroxyl and carbonyl group upon exposure to air or oxygen (Column 14, lines 1-67). Kanbe teach that the polar group have and affinity to fluid containing polar molecules (column 14, lines 9-10). Therefore, Kanbe *et al* disclose a substrate wherein the substrate comprises a non-uniform plama polymerized surface.

Kanbe *et al* teach that the invention provides a region of the surface of a substrate having an affinity to a fluid and a region not having an affinity to a fluid (column 14, lines 9-10 and column 24, lines 52-57), but fail to teach binding of biomolecules (e.g. cells) to the affinity region.

Haddow *et al* disclose plasma polymerized surface having functional groups (e.g. carboxylic acid, alcohol) (page 4, lines 1-2) useful for adhering and culturing cells (abstract and page 4, lines 28-30). Haddow *et al* teach that by plasma polymerization, it is possible to modify surface chemistry without affecting the bulk

properties of the substrate and to deposit a range of different types of surfaces (page 4, lines 18-24) and is advantageous because the surface have unique chemical and physical characteristics (page 3, lines 3-4 and page 4, lines 25-26). Haddow *et al* teach the surface produced by plasma polymerization is particularly useful as a substrate for cell culture (page 5, lines 21-25; page 13, lines 13-25).

Uhrich *et al* teach patterned areas of a substrate for making patterns of biologically active molecules useful for spatially directing cell growth, tissue regeneration, screening studies and multiple analytical biosensor (see abstract and paragraph [0002]).

Therefore, given the fact that plasma polymerized surface is useful for adhering and growth of cells (Haddow *et al*) and culturing of cells in a pre-selected region (i.e. patterned surface) is very useful and known in the art (Uhrich *et al*), it would be obvious to one of ordinary skill in the art at the time the invention was made to consider the patterned surface of Kanbe *et al* for adhering of cells because Haddow *et al* teach plasma polymerized surface is useful for cell attachment and culture and because different surface (i.e. surface groups) can be produced by plasma polymerization with ease. It would also be obvious from the teaching of Haddow *et al* that various functional groups can be introduced into the un-masked region of Kanbe *et al* by plasma polymerization using different polymerisable monomers with the expectation of providing the pattened surface of Kanbe *et al* with different functional groups as needed for attachment of various biomolecules.

With regard to claims 45 and 46, Haddow et al teach attachment of cells to plasma polymerized surface (page 4, lines 1-2, 18-20 and page 5, lines 17-27) and cells comprises carboxyl or amine functional group.

With regard to claims 49-53, Haddow *et al*, as described above, teach various functional groups capable of interacting and linking with cells and binding entity and different binding events with various groups on the surface would be obvious to one of ordinary skill in the art.

With regard to claim 55, Haddow *et al* teach use of volatile acid (Page 6, lines 10-11).

With regard to claims 62 and 65, Haddow *et al* teach polymer comprising single monomer (page 3, lines 10-25; page 6, lines 21-31 and page 7, lines 24-30) which can be carboxylic acid (page 7, lines 24-25) and with regard to claim 68, copolymer is disclosed by Haddow *et al* (page 3, lines 26-30).

With regard to claim 70, Haddow *et al* disclose polymerizable monomers having vapour pressures of at least $6.6X10^{-2}$ mbar (page 7, lines 9-12).

With regard to claims 71-72 and 74, Kanbe *et al* teach various shapes of patterned surface (see Figs. 2 and 4).

With regard to claim 75, Kanbe *et al* teach that the base 100 can be polyethylene oxide (column 10, line 59) and thus the non-plasma treated region (i.e. masked region) would comprise polyethylene oxide.

With regard to claims 76, Kanbe *et al* disclose that the substrate can be glass or plastic (column 14, line 4) and with regard to claim 77, Haddow *et al* teach substrate comprising polyethylene (page 5, lines 1-7).

With regard to claim 79, Haddow *et al*, as described above, teach the system can be used for cell adherence and cell culture (page 21, lines 18-20) and thus is considered as a cell culture system.

With regard to claims 80-83, Ulridh *et al* teach that micro patterned substrates is useful for various biological applications including biological assays, medical implants and articles for adhering and growing cells (paragraph [0002]) and once the method to provide a micro pattern surface in known, use of the surface in various system would be within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a).

With regard to claim 84, Uhrich *et al* teach that the patterned substrate is useful for cell growth, screening strategies (paragraph [0002]), detection and identification of molecular species, macromolecules, biomolecules, cells and tissues (paragraph [0035]) and since plasma polymerization, as described above is useful for providing various reactive groups, it would be obvious to one of ordinary skill in the art to envision screening binding properties of biomolecules by identifying binding of the biomolecules (e.g. cells) at different reactive groups on the patterned surface, with a reasonable expectation of success.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAFIQUL HAQ whose telephone number is (571)272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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